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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,805	11/01/2001	Brian T. Wimberly	22620/1132	5939
29933	7590	12/15/2003		
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199			EXAMINER SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

10

Office Action Summary	Application No.	Applicant(s)	
	09/998,805	WIMBERLY ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 7-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) ☐ Other: _____ .

DETAILED ACTION

Applicant's amendments and remarks, filed 10/28/03, are acknowledged. Amended claims 1 and 4 are acknowledged.

Applicant's arguments, filed 10/28/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-6 are herein under examination.

Claims Rejected Under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

There does not appear to be adequate support for the amended portion of claim 1 which includes "wherein said contacting comprises contacting by computer modeling or by physically

Art Unit: 1631

contacting said potential modulator with the L11/GAR, wherein a modulator of L11/GAR activity is identified.” Written basis is analyzing potential *modulating* or *binding effect* of a chemical compound on the L11/GAR via computer modeling (page 40, lines 2-3 of the specification), but not for the broadly mentioned “*contacting* by computer modeling”, as now stated in the claim 1, lines 9-10. Written basis is also provided for a compound physically and structurally *associating with* L11/GAR (page 39, lines 15-16 of the specification), but not necessarily *physically contacting* said potential modulator with the L11/GAR which differs in scope, as now stated in claim 1, lines 10-11. The added portion of what “contacting” comprises of as newly stated on lines 9-11 is not adequately supported in the specification, drawings, or claims as originally filed. Because the introduction of “wherein said contacting comprises contacting by computer modeling or by physically contacting said potential modulator with the L11/GAR, wherein a modulator of L11/GAR activity is identified” lacks written basis for amended claim 1, as filed on 10/28/03, it is considered NEW MATTER. Claims 2-6 are also rejected due to their direct or indirect dependency from claim 1. This rejection is necessitated by amendment.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

The rejection of claims 1-6 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (lines 2, 3, 4, 8, 9, and 11) and 4 (line 5) are vague and indefinite due to the unclarity of citing an abbreviation, L11/GAR. Correction is suggested by amending in of the full name in parentheses. Claims 2, 3, 5, and 6 are also rejected due to their dependence from claims 1 and 4.

Applicants state pages in the specification where the terms "GAR" and "L11/GAR" are defined. While this statement is acknowledged, it is noted that agency practice is to cite the full name of any abbreviations stated in the claims in parentheses, so that the claims clearly describe the invention.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

Art Unit: 1631

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-6 is maintained under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (P/N 6,160,092), in view of *In re Gulack* (703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)).

Chen et al. describe a method for identifying an agent that enhances or diminishes the activity of a protein (col. 4, lines 56-60). Chen et al. describe determining the three-dimensional structure of a compound based on structural coordinates obtained from X-ray crystallographic analysis of crystals (col. 4, lines 14-22). Chen et al. describe using computer modeling to select potential agents and contacting the agents with the protein (col. 4, col. 21-26). Chen et al. describe determining whether the agent affects the ability of the protein to induce expression of a gene that is operably under the control of a promoter containing the binding site for the protein (col. 4, lines 56-50). Chen et al. describe the potential modulator can be synthesized de novo or selected from a library of chemicals (col. 23, lines 13-24). Chen et al. describe that the proteins and core fragments thereof may be chemically synthesized (col. 19, lines 21-24) and modified (col. 5, lines 38-39). This core region includes the binding site for the protein dimer (abstract, lines 1-3). Chen et al. describe identifying potential modulators by screening a random peptide library and further modified using computer modeling programs (col. 22, lines 51-59). Even though the method described by Chen et al. does not specify that the active site was identified by the crystal structure coordinates and the three-dimensional model of the ribosomal protein L11/GAR RNA complex, the specific limitations of crystal structure coordinates and the three-dimensional model of the L11/GAR complex in this instant case do not distinguish the invention

Art Unit: 1631

from the prior art in terms of patentability, because they are nonfunctional descriptive subject matter.

In re Gulack defines nonfunctional descriptive material to be descriptive material that is not functionally related to the substrate, in such a way that this descriptive material will not distinguish the invention from the prior art in terms of patentability. Also, the MPEP indicates that descriptive material unable to exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106, section VI). Due to the fact that the coordinate data set derived from the crystal structure of the L11/GAR complex to develop three-dimensional models in the instant case are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, this descriptive material alone does not impart functionality either to the data as structured, or to the computer. As the invention of Chen et al. contains a method for identifying agents that interact with a protein and various modifications to their invention would be apparent to a skilled artisan (col. 38, lines 2-5), a skilled artisan would have been motivated to include any crystalline protein already identified into this method in order to search for new drugs (col. 3, lines 5-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the three-dimensional model of the L11/GAR complex in the method, in order to search for possible drug candidates, as described by Chen et al. (col. 4, lines 32-38). Thus, Chen et al., in view of *In re Gulack*, motivate the instant invention.

Art Unit: 1631

The rejection of claims 1-6 is maintained under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (P/N 6,160,092), in view of Hinck et al. (Journal of Molecular Biology, 1997, Vol. 274, pp. 101-113) and *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594).

Chen et al. describe a method for identifying an agent that enhances or diminishes the activity of a protein (col. 4, lines 56-60). Chen et al. describe determining the three-dimensional structure of a compound based on structural coordinates obtained from X-ray crystallographic analysis of crystals (col. 4, lines 14-22). Chen et al. describe using computer modeling to select potential agents and contacting the agents with the protein (col. 4, col. 21-26). Chen et al. describe determining whether the agent affects the ability of the protein to induce expression of a gene that is operably under the control of a promoter containing the binding site for the protein (col. 4, lines 56-50). Chen et al. describe the potential modulator can be synthesized de novo or selected from a library of chemicals (col. 23, lines 13-24). Chen et al. describe that the proteins and core fragments thereof may be chemically synthesized (col. 19, lines 21-24) and modified (col. 5, lines 38-39). This core region includes the binding site for the protein dimer (abstract, lines 1-3). Chen et al. describe identifying potential modulators by screening a random peptide library and further modified using computer modeling programs (col. 22, lines 51-59). Chen et al. do not describe the three-dimensional structure of the L11/GAR complex.

Hinck et al. describe a three-dimensional structure of the RNA binding domain of ribosomal protein L11 as determined by NMR (abstract). Although Hinck et al. do not describe the atomic coordinates of the L11/GAR according to Table II, as stated in claim 1 (lines 3-4), this limitation appears to be merely an additional measurement made of the same L11/RNA complex as described by Hinck et al.

Art Unit: 1631

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter shown to be in the prior art does not possess characteristic relied on” (205 USPQ 594, second paragraph, first full paragraph).

As the invention of Chen et al. contains a method for identifying agents that interact with a protein and various modifications to their invention would be apparent to a skilled artisan (col. 38, lines 2-5), a skilled artisan would have been motivated to include any crystalline protein complex already identified into this method in order to search for new modulators (col. 3, lines 5-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the three-dimensional model of the L11/GAR complex (as stated by Hinck et al.) in the method, in order to search for possible drug candidates, as described by Chen et al. (col. 4, lines 32-38). Thus, Chen et al., in view of Hinck et al. and *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594), motivate the instant invention.

The 103(a) rejections are maintained on the assumption that the amended portion of claim 1 will be removed due to the presence of NEW MATTER.

Chen et al. in view of *In re Gulack*

Applicants submit that in order to render a claimed invention obvious, the cited references must teach or suggest all elements of the recited claim. Applicants state that Chen et al. do not teach the atomic coordinates for L11/GAR according to Table II of the instant

Art Unit: 1631

specification as recited in claim 1. This is found unpersuasive as the atomic coordinates of any crystal structure are considered nonfunctional descriptive material in a method such as that stated by Chen et al. The fact that the atomic coordinates of L11/GAR and STAT are not the same is irrelevant in this case as they are merely nonfunctional descriptive material that fail to exhibit any functional interrelationship with the way in which the computing process is performed.

Applicants submit the reasoning that the atomic coordinates of the L11/GAR were already known is an incorrect presumption as the coordinates were not available in the prior art. However, the atomic coordinates were known at the time the invention was made (since they are part of the instant invention), and therefore it would have been obvious to use these coordinates or any other atomic coordinates from synthesized crystals at the time of the invention.

Applicants disagree that the atomic coordinates are nonfunctional descriptive material. Applicants further state that computer modeling programs require data in order to produce a model which can then be used to design or predict interacting molecules. This is found unpersuasive as the coordinates are considered nonfunctional descriptive material since they do not exhibit any functional interrelationship with the way the computing processes are performed as stated in MPEP § 2106, section VI. In other words, the same type of computing process occurs regardless of the type of coordinates are entered into the process.

Therefore, the 103(a) rejection of Chen et al. in view of *In re Gulack* is maintained.

Chen et al. in view of Hinck et al., *In re Best* and *In re Fitzgerald*

Applicants submit the atomic coordinates were not known in the art at the time the invention was made. Applicants submit the statement that the atomic coordinates of the

Art Unit: 1631

L11/GAR are inherent in the NMR structure of L11/GAR is incorrect based on resolution differences. This is found unpersuasive as instant claim 1 recites using a three-dimensional structure. Therefore, the claim can be broadly and reasonably interpreted to mean any three dimensional structure, including one determined by NMR. Claim 1 recites “using a three-dimensional structure of the L11/GAR complex as defined by atomic coordinates of the L11/GAR according to Table II”. A broad and reasonable interpretation of this phrase includes any three dimensional structure of L11/GAR, because the “as defined by atomic coordinates of the L11/GAR according to Table II” portion of the claim is merely an additional measurement that is characteristic of L11/GAR. The three-dimensional structure of this claim does not necessarily contain these coordinates as these coordinates are currently written as defining the complex (inherent characteristic) but not necessarily the three dimensional structure itself.

Therefore, the 103(a) rejection of Chen et al. in view of Hinck et al., *In re Best* and *In re Fitzgerald* is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1631

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 10, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER